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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313 on September 21, 2006.

Margaret Efron, Patent Attorney

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 CFR 1.322
Docket No. UF-375
Patent No. 7,084,111

SEP 25 2006
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Carrie Haskell-Luevano
Issued	:	August 1, 2006
Patent No.	:	7,084,111
For	:	Melanocortin Receptor Templates, Peptides, and Use Thereof

Mail Stop Certificate of Corrections Branch
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Certificate
SEP 27 2006
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION
UNDER 37 CFR 1.322 (OFFICE MISTAKE)

Sir:

A Certificate of Correction (in duplicate) for the above-identified patent has been prepared and is attached hereto.

In the left-hand column below is the column and line number where errors occurred in the patent. In the right-hand column is the page and line number in the application where the correct information appears.

The applicant notes that the amendments made in the Examiner's Amendment dated March 10, 2006, which accompanied the Notice of Allowability, contain typographical errors. The applicant submits herewith a copy of the Examiner's Amendment dated March 10, 2006.

Additionally, a true and correct copy of page 2 of the Preliminary Amendment dated January 25, 2006, which supports the applicant's assertion of a separate error on the part of the Patent Office, accompanies this Certificate of Correction.

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SEP 29 2006

Patent Reads:	**Application Reads:**
Column 13, lines 24-25:	See Preliminary Amendment dated January 25, 2006, Page 2:
"benzotriazole-2-yloxy-tris-(dimethylamino)"	--benzotriazole-1-yloxy-tris-(dimethylamino)--
Column 49, line 3:	See Examiner's Amendment dated March 10, 2006, Page 3:
"Xaa2 is selected from Trp, Phe, DPhe, Ala, Ato, Bip, Lys,"	--Xaa2 is selected from Trp, Phe, DPhe, Ala, Atc, Bip, Lys,--
Column 50, line 13:	See Examiner's Amendment dated March 10, 2006, Page 4:
"Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys,"	--Xaa2 is selected from Trp, Phe, DPhe, Ala, Atc, Bip, Lys,--

Approval of the Certificate of Correction is respectfully requested.

Respectfully submitted,

Margaret Efron
Patent Attorney
Registration No. 47,545
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

MHE/an

Attachments: Certificate of Correction (in duplicate);
Copy of Page 2 of Preliminary Amendment dated January 25, 2006; and
Copy of Examiner's Amendment dated March 10, 2006.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,084,111

APPLICATION NO.: 10/602,394

DATED : August 1, 2006

INVENTOR : Carrie Haskell-Luevano

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13,
Lines 24-25, "benzotriazole-2-yloxy-tris-(dimethylamino)"
should read --benzotriazole-1-yloxy-tris-(dimethylamino)--.

Column 49,
Line 3, "Xaa2 is selected from Trp, Phe, DPhe, Ala, Ato, Bip, Lys,"
should read --Xaa2 is selected from Trp, Phe, DPhe, Ala, Atc, Bip, Lys,--.

Column 50,
Line 13, "Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys,"
should read --Xaa2 is selected from Trp, Phe, DPhe, Ala, Atc, Bip, Lys,--.

MAILING ADDRESS OF SENDER:
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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 7,084,111

APPLICATION NO.: 10/602,394

DATED : August 1, 2006

INVENTOR : Carrie Haskell-Luevano

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 13,
Lines 24-25, "benzotriazole-2-yloxy-tris-(dimethylamino)"
should read --benzotriazole-1-yloxy-tris-(dimethylamino)--.

Column 49,
Line 3, "Xaa2 is selected from Trp, Phe, DPhe, Ala, Ato, Bip, Lys,"
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Column 50,
Line 13, "Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys,"
should read --Xaa2 is selected from Trp, Phe, DPhe, Ala, Atc, Bip, Lys,--.

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SEP 25 2006
PATENT & TRADEMARK OFFICE

I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office on the date shown below:

January 25, 2006

Margaret Efron, Patent Attorney

PRELIMINARY AMENDMENT
UNDER 37 CFR §1.115
Examining Group 1654
Patent Application
Docket No. UF-375
Serial No. 10/602,394

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner	:	Satyanarayan R. Gudibande
Art Unit	:	1654
Applicant	:	Carrie Haskell-Luevano
Serial No.	:	10/602,394
Conf. No.	:	1696
Filed	:	June 23, 2003
For	:	Novel Melanocortin Receptor Templates, Peptides, and Use Thereof

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRELIMINARY AMENDMENT UNDER 37 CFR §1.115

Sir:

Please amend the above-referenced application as follows:

Amendments to the Specification begin on page 2 of this paper.

Remarks/Arguments follow the amendment section of this paper.

SEP 29 2006

In the Specification

Please amend the paragraph beginning at page 18, line 16 through page 19, line 3 as follows:

The growing peptide chain was added to the amide-resin using the general amino acid cycle as follows: 500 μL DMF is added to each reaction well to "wet the frit," 3-fold excess amino acid starting from the C-terminus is added [~~400 μM~~ 400 μL of 0.5M solution in 0.5M N-hydroxybenzotriazole (HOBt) in DMF] followed by the addition of 400 μL 0.5M N,N'-diisopropylcarbodiimide (DIC) in DMF and the reaction well volume is brought up to 3mL using DMF. The coupling reaction is mixed for 1hr at 500 rpms, followed by emptying of the reaction block by positive nitrogen gas pressure. A second coupling reaction is performed by the addition of 500 μL DMF to each reaction vessel, followed by the addition of 400 μL of the respective amino acid (3-fold excess), 400 μL 0.5M O-benzotriazolyl-N,N,N',N'-tetramethyluronium hexafluorophosphate (HBTU), 300 μL 1M DIEA, the reaction well volume is brought up to 3 mL with DMF, and mixed at 500 rpm for 1 hr. After the second coupling cycle, the reaction block is emptied and the resin-Nα-protected peptide is washed with DCM (4.5 mL 4 times). Nα-Boc deprotection is performed by the addition of 4 mL 50% TFA, 2%anisole in DCM and mixed for 5 min at 500 rpms followed by a 20 min deprotection at ~~20 min~~ 500 rpm. The reaction well is washed with 4.5 mL DCM (4 times), neutralized with 10% DIEA (3 min, 500 rpms, 2 times) followed by a DCM wash (4.5 mL, 2 min, 500 rpms 4 times), and the next coupling cycle is performed as described above.

Please amend the paragraph at page 19, lines 4-13 as follows:

The Fmoc and OFm protecting groups are removed from Dpr and Asp, respectively by treatment with 4.5 mL 25% piperidine in DMF (20 min at 500 rpm) with a positive Kaiser test results. The lactam bridge between the Asp and Dpr amino acids is formed using 5-fold excess benziotriazole-1-yloxy-tris-(dimethylamino) phosphonium hexafluorophosphate (BOP) and 6-fold

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DETAILED ACTION

Previous office action dated March 10, 2006 is vacated in lieu of this office action.

Election/Restrictions

Applicant's election of group I invention (claims 1-8 and 13-20) in the reply filed on January 25, 2006 is acknowledged. Canceling of claims 4, 9-12, 16 and 21-27 and addition of claim 28 via a preliminary amendment filed on December 20, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Examiner searched Seq ID No. 3 and found to be free of art. Examiner continued the search to other species and found them to be free of art.

Claim 28 was included in the examination of the instant application.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Margaret Efron on March 02, 2006.

The application has been amended as follows:

IN THE CLAIMS:

Cancel claims 1-3, 5-8, 13-15, 17-20 and 28.

Enter new claims 29-43 as follows:

29. A peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3 wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with a melanocortin agonist-based bioactive determinant sequence wherein
a) the melanocortin agonist-based bioactive determinant sequence is selected from the group consisting of:
i) Trp-Arg-Phe
ii) Trp-Arg-DPhe
iii) Phe-Arg-Trp
iv) DPhe-Arg-Trp
v) His-Phe-Arg-Trp; and
vi) His-DPhe-Arg-Trp.

30. The peptide according to claim 29, wherein the peptide is of any SEQ ID Nos. 4-7, 9 and 10.

31. A peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3, wherein AGRP (111-113) residues of the AGRP(109-118) template are substituted with the sequence

Xaa1-Xaa2-Xaa3-Xaa4

wherein Xaa1 is selected from His, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic, or is absent;
Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic,
Xaa3 is selected from Arg, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic;
Xaa4 is selected from Phe, DPhe, Trp, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic; and
wherein, at least one of Xaa1, Xaa2, Xaa3 or Xaa4 is selected from Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic.

32. A peptide that is biologically active at melanocortin receptors comprising a sequence selected from the group consisting of SEQ ID Nos: 2 and 24-43.

33. The peptide according to claim 29, wherein the peptide further comprises a lactam bridge that is substituted for the disulfide bridge of the AGRP (109-118) analogue template.

34. The peptide according to claim 33, wherein the peptide is SEQ ID No: 11.

35. The peptide according to claim 33, wherein the peptide further comprises a second and a third bioactive determinant sequences at the N-terminal and C-terminal, respectively, wherein the second bioactive determinant sequence at the N-terminal is Ser-Tyr-Ser-Nle (amino acid residues 2-5 of SEQ ID No: 11) and the third bioactive determinant sequence at the C-terminal is Lys-Pro-Val amino acid residues.

36. A pharmaceutical composition comprising a peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID No: 3 wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with a melanocortin agonist-based bioactive determinant sequence wherein
a) the melanocortin agonist-based bioactive determinant sequence is selected from the group consisting of:
i) Trp-Arg-Phe
ii) Trp-Arg-DPhe
iii) Phe-Arg-Trp
iv) DPhe-Arg-Trp
v) His-Phe-Arg-Trp; and
vi) His-DPhe-Arg-Trp.

37. The pharmaceutical composition according to claim 36, wherein the peptide is of any SEQ ID Nos. 4-7, 9 and 10.

38. A pharmaceutical composition comprising a peptide that is biologically active at melanocortin receptors comprising an AGRP (109-118) analogue template of SEQ ID NO: 3, wherein AGRP (111-113) residues of the AGRP (109-118) template are substituted with the sequence

Xaa1-Xaa2-Xaa3-Xaa4

wherein,
Xaa1 is selected from His, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic, or is absent;
Xaa2 is selected from Trp, Phe, DPhe, , Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic,
Xaa3 is selected from Arg, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic;
Xaa4 is selected from Phe, DPhe, Trp, Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic; and
wherein, at least one of Xaa1, Xaa2, Xaa3 or Xaa4 is selected from Ala, Atc, Bip, Lys, Nal(1'), Nal(2'), (pI)Phe and Tic.

39. A pharmaceutical composition comprising a peptide of claim 32.

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40. The pharmaceutical composition according to claim 36, wherein the peptide further comprises a lactam bridge that is substituted for the disulfide bridge of the AGRP (109-118) analogue template.

41. The pharmaceutical composition according to claim 40, wherein the peptide is of SEQ ID No. 11.

42. The pharmaceutical composition according to claim 40, wherein the peptide further comprises a second and a third bioactive determinant sequences at the N-terminal and C-terminal, respectively, wherein the second bioactive determinant sequence at the N-terminal is Ser-Tyr-Ser-Nle (amino acid residues 2-5 of SEQ ID No: 11) and the third bioactive determinant sequence at the C-terminal is Lys-Pro-Val amino acid residues.

43. The composition of claim 36, wherein the composition is an oral composition.

Reasons for Allowance

In the instant application, applicants claim a peptide that is biologically active at melanocortin receptors comprising an AGRP(109-118) analog template of Seq ID No: 3, wherein AGRP(111-113) residues of the AGRP(109-118) template are substituted with a melanocortin agonist based bioactive determinant sequence.

The following is an examiner's statement of reasons for allowance: The closest prior art, Tota, et al., Biochemistry, 1999, 38, 897-904 teaches the molecular interaction of AGRP and AGRP related proteins with human melanocortin receptors. However, the prior art does not teach or suggest, alone or in combination, the instantly claimed peptide sequences that are biologically active at melanocortin receptors.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Satyanarayana R. Gudibande, Ph.D.
Art Unit 1654

Bruce Campell

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600